K090289

510(k) SUMMARY

JUN 15 2009

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

OrthoHelix Surgical Designs, Inc.
1815 W. Market
Akron, Ohio 44313
Phone: (330) 869-9582
Fax: (330) 869-9583

Contact Person: Derek Lewis
Vice President of Research and Development

Date Prepared: January 21, 2009

Name of Device

Clavicle Plating System

Common or Usual Name

Fixation Plates

Classification Name

Plate, Fixation, Bone

Predicate Devices

The Clavicle Plating System is substantially equivalent to currently marketed devices.

Intended Use

The Clavicle Plating System is indicated for fractures, fusions and osteotomies of the clavicle and small bones in the hand, wrist, foot and ankle.

Device Description

The OrthoHelix Clavicle Plating System is a set of metallic, implantable, bone fixation plates. The CPS includes universal plates and indication specific plates of different sizes. All plates are made from implant grade titanium alloy.

Substantial Equivalence

Finite Element Analysis and mechanical testing confirm that the implants within the Clavicle Plating System are substantially equivalent to its predicate devices, and that it meets the specified requirements for its intended use. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2009

OrthoHelix Surgical Designs, Incorporated
% Mr. Derek Lewis
Vice President of Research and Development
1815 W. Market St., Suite 205
Akron, Ohio 44313

Re: K090289
Trade/Device Name: Clavicle Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: May 29, 2009
Received: June 10, 2009

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson

Mark N. Melkerson
Director
Division of Surgical, Orthopedic, and
Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090289

Indications for Use

510(k) Number (if known): TBD

Device Name: Clavicle Plating System

Indications for Use:

The OrthoHelix Clavicle Plating System Plates are indicated for fixation of fractures, fusions and osteotomies of the clavicle and small bones in the hand, wrist, foot and ankle.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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